NSK

K113530

5. 510(k) SUMMARY

JAN 31 2013

Submitter:	Nakanishi, Inc. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Mr. Toshihiko Shinozaki Assistant Manager, R&D Dept. Pharmaceutical Affairs Gr. TEL: 0289(64)3380 FAX: 0289(62)6665 t-shinozaki@nsk-nakanishi.co.jp
Application Correspondent:	Ms. Diane Rutherford Ken Block Consulting TEL: 972-480-9554 FAX: 972-767-4325 rutherford@kenblockconsulting.com
Date Prepared:	November 23, 2011
Trade Name:	Varios 970 / Varios 970 Lux
Common Name:	Ultrasonic Scaler
Classification Name:	ELC 872.4850 Scaler, Ultrasonic
Predicate Device:	K071447 – Nakanishi Varios 75
Device Description:	Varios 970 is a stand-alone ultrasonic scaler device powered by the iPiezo® engine. The Varios 970 consists of the Varios 970 Control Unit, two independent 400 mL irrigation bottles, handpiece, and a wide range of tip inserts. The tip inserts, when attached at the distal end of the handpiece transducer, resonate at ultrasonic frequencies of 28 -32 kHz. The 400 mL bottles each can carry different solutions with independent pumps. The Varios 970 LUX features twin LED lights that last longer, are more durable, and generate less heat than halogen bulbs.
Statement of Intended Use:	This device, Varios 970, an electronic ultrasonic scaler, is intended for use with an appropriate tip for following use: – Scaling, Perio, Implant Maintenance, Endodontic, Retrograde Endo, Restorative (for Minimal Intervention/ Finishing/Trimming/ Polishing/Caries of Dentin), Prosthetics (Condensation / Loosening / Plugging)
Summary of Technological Characteristics:	Both the Varios 970 and the predicate Varios75 utilize the iPiezo engine to generate ultrasonic frequencies of 28 -32 kHz. Both have the same operating modes, irrigation modes, and operating time. During the mode of operation, a sinusoidal electrical signal, at ultrasonic frequency (f > 20kHz), is generated and delivered to the 'piezoelectric ceramic' located inside the handpiece transducer. The electrical signal is converted into mechanical vibrations and propagated to the distal end of the handpiece.
Summary of Test Data:	The Varios 970 has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for sterilization.
Conclusion:	Nakanishi, Inc. considers the Varios 970 Ultrasonic Scaler to be substantially equivalent to the predicate device (Varios 75) listed above. This conclusion is based on the similarities in primary intended use, principles of operation, design rationale, and performance.

NAKANISHI INC. Headquarters : 700 Shimohihata Kanuma-shi Tochigi 322-8666, Japan
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2013

Nakanishi, Incorporated
C/O Ms. Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

Re: K113530
Trade/Device Name: Varios 970 / Varios 970 Lux
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 28, 2013
Received: January 29, 2013

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

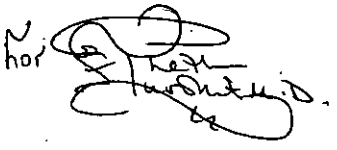
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K113530

Device Name: Varios 970 / Varios 970 Lux

Indications for Use:

This device, Varios 970 / Varios 970 Lux, an electronic ultrasonic scaler, is intended for use with an appropriate tip for following use:

- *Scaling, Perio, Implant Maintenance, Endodontic, Retrograde Endo, Restorative (for Minimal Intervention/ Finishing/Trimming/ Polishing/Caries of Dentin), Prosthetics (Condensation / Loosening / Plugging)*

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

Andrew I. Steen
2013.01.31 13:29:47 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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